JUN 22 2010

5. 510(K) SUMMARY K101345

Applicant:

Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765
USA
Phone: 800-729-7272
Fax: 909-839-8804

Date: May 11, 2010

Contact Person:

Balaka Das
Senior Specialist, Regulatory Affairs

Proprietary Device Name: Webster CS Catheter with EZ Steer Technology
Webster CS Catheter with EZ Steer Technology and Auto ID

Common Device Name: Electrophysiology Mapping Catheter

Classification Name: Electrode Recording Catheter
(per 21 CFR 870.1220, Product Code DRF)

Predicate Device: Webster CS Catheter with EZ Steer Technology
Webster CS Catheter with EZ Steer Technology and Auto ID

Manufacturing Facilities:

Biosense Webster, Inc.
15715 Arrow Highway
Irwindale, CA 91706 USA

Biosense Webster, Inc.
Circuito Interior Norte #1820
Parque Industrial Salvacar
Juarez, Chihuahua, Mexico, 32599

5.1 Substantially Equivalent To:

Webster CS Catheters with EZ Steer Technology and Webster CS Catheters with EZ Steer Technology and Auto ID cleared via 510(k) K090898 cleared on September 4, 2009.

5.2 Description of the Device Subject to Premarket Notification:

The Webster Coronary Sinus Catheter with EZ Steer Bi-directional Technology (D-1263-04 & D-1263-05)

The Webster CS Catheters with EZ Steer Bi-directional Technology (D-1263-04 & D-1263-05) are diagnostic, 7Fr, deflectable, mapping electrophysiology (EP) catheters with the ability to map electrical activity within the Coronary Sinus through distal Platinum/Iridium electrodes located along the catheter's pre-shaped tip. The catheters incorporate a 2 mm tip electrode, 10 total electrodes, 2-8-2 mm electrode spacing, have bi-directional deflection and are 115 cm long. These catheters include a braided bi-directional deflectable tip section. The braided bi-directional tip provides the user with two 180° opposed single plane curves. Currently, the available curves include FJ (D-1263-04) and DF (D-1263-05). These catheters include a handle with a Rocker Lever, which is used to deflect the tip. The high-torque shaft allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site. The following cables are used to provide a means for interface of the catheters with the appropriate equipment:

- D-1221-21
- D-1221-26
- D-1221-25

The Webster Coronary Sinus Catheter with EZ Steer Bi-directional Technology and Auto ID
(D-1263-06 & D-1263-07)

The Webster CS Catheters with EZ Steer Bi-directional Technology (D-1263-06 & D-1263-07) are diagnostic, 7Fr, deflectable, mapping electrophysiology (EP) catheters with the ability to map electrical activity within the Coronary Sinus through distal Platinum/Iridium electrodes located along the catheter's pre-shaped tip. The catheters incorporate a 2 mm tip electrode, 10 total electrodes, 2-8-2 mm electrode spacing, have bi-directional deflection and are 115 cm long. These catheters include a braided bi-directional deflectable tip section. The braided bi-directional tip provides the user with two 180° opposed single plane curves. Currently, the available curves include FJ (D-1263-06) and DF (D-1263-07). These catheters include a handle with a Rocker Lever which is used to deflect the tip. The high-torque shaft allows the plane of the curved tip to be rotated to facilitate accurate positioning of the catheter tip at the desired site.

The Webster CS Catheters with EZ Steer Bi-directional Technology and Auto ID (D-1263-06 & D-1263-07) are equipped with Electronically Erasable Programable Read Only Memory (EEPROM) which is used to store unique catheter identification information.

[redacted]

Carto EP Navigation Systems equipped with Auto ID Technology can access the stored information and automatically recognize the catheter information.

The catheters interface with Carto EP Navigation Systems via an interface cable (D-1286-16) with the appropriate connectors.

5.3 Indications for Use:

The Webster CS Catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only. The catheter is designed for use in the coronary sinus.

5.4 Performance Data:

The Webster CS Catheters have passed bench testing to validate the mechanical and electrical integrity of the catheters and the performance of the catheters with the ancillary equipment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

JUN 22 2010

Biosense Webster, Inc.
c/o Ms. Balaka Das
Senior Specialist, Regulatory Affairs
3333 Diamond Canyon Road
Diamond Bar, CA 91765

Re: K101345
Trade/Device Name: Webster CS Catheter with EZ Steer Technology; and, Webster CS Catheter with EZ Steer Technology and Auto ID.
Regulatory Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: II (two)
Product Code: 74 DQO
Dated: May 11 2010
Received: May 13, 2010

Dear Ms. Das:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. J. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) No (if known): K101345

Device Name:

- Webster CS Catheter with EZ Steer Technology
  (D-1263-04 & D-1263-05)
- Webster CS Catheter with EZ Steer Technology and Auto ID
  (D-1263-06 & D-1263-07)

Indications for Use:

The Webster CS Catheter is indicated for electrophysiological mapping of cardiac structures; i.e., stimulation and recording only. The catheter is designed for use in the coronary sinus.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101345